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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,400	02/27/2004	Peter L. Collins	4239-67784-01	5376

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,400	COLLINS ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 25, 26, 55 and 56, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modification comprising a partial or complete deletion of a HMPV SH ORF such that a wild type SH protein is not produced, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and an expression vector comprising the partial or complete rHMPV genome or antigenome under the control of a promoter, classified in class 424, subclasses 199.1 and 205.1.

II. Claims 1-8, 11, 12, 25, 26, 55 and 56, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modification comprising a partial or complete deletion of a HMPV G ORF such that a wild type G protein is not produced, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and an expression vector comprising the partial or complete rHMPV genome or antigenome under the control of a promoter, classified in class 424, subclasses 199.1 and 205.1.

III. Claims 1-8, 13, 14, 25, 26, 55 and 56, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide

modification comprising a partial or complete deletion of a HMPV SH and G ORFs such that wild type SH and G proteins are not produced, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and an expression vector comprising the partial or complete rHMPV genome or antigenome under the control of a promoter, classified in class 424, subclasses 199.1 and 205.1.

IV. Claims 1-8, 15-19, 25, 26, 55 and 56, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modification comprising one or more nucleotide substitution that reduces or ablates expression of rHMPV M2-2 ORF such that a wild type M2-2 protein is not produced, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and an expression vector comprising the partial or complete rHMPV genome or antigenome under the control of a promoter, classified in class 424, subclasses 199.1 and 205.1.

V. Claims 1-8, 20-22, 25-27, 55 and 56, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modification comprising one or more nucleotide substitution that reduces or ablates expression of rHMPV M2-1 ORF such that a wild type M2-1 protein is not produced, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and an expression vector

comprising the partial or complete rHMPV genome or antigenome under the control of a promoter, classified in class 424, subclasses 199.1 and 205.1.

VI. Claims 1-8, 23-26, 55 and 56, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modification comprising a partial or complete deletion of a HMPV M2 ORF, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and an expression vector comprising the partial or complete rHMPV genome or antigenome under the control of a promoter, classified in class 424, subclasses 199.1 and 205.1.

VII. Claims 28-31, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), wherein the genome or antigenome is rearranged such that an order of one or more genes or genome segments is altered as compared to a wild type HMPV, and wherein a SH gene and a G gene or at least two copies of SH gene and at least two copies of G gene are inserted after a M gene and before a F gene, classified in class 424, subclasses 199.1 and 205.1.

VIII. Claims 28, 29 and 32-35, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), wherein the genome or

antigenome is rearranged such that an order of one or more genes or genome segments is altered as compared to a wild type HMPV, and wherein a F gene or a G gene or both a F gene and a G gene are inserted after a 3' leader sequence and before a N gene in the rHMPV genome or antigenome, classified in class 424, subclasses 199.1 and 205.1.

IX. Claims 36-42, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modifications, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), wherein the one or more attenuating nucleotide modifications comprises inserting one or more additional copies of one or more rHMPV G or F genes or both after a 3' leader sequence and before a N gene in the rHMPV genome or antigenome, classified in class 424, subclasses 199.1 and 205.1.

X. Claims 43-46, drawn to an isolated recombinant human metapneumovirus (rHMPV) comprising a partial or complete recombinant HMPV genome or antigenome comprising one or more attenuating nucleotide modifications, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), wherein the rHMPV further comprises one or more heterologous genes or genome segments from a different paramyxovirus to form chimeric recombinant HMPV genome or antigenome, classified in class 424, subclasses 199.1 and 211.1.

XI. Claims 47-51, drawn to an immunogenic composition comprising the isolated replication competent rHMPV of claim 1, and a method for inducing an immune response in a subject by administering to the subject said rHMPV, classified in class 424, subclass 93.1.

XII. Claims 52-54, drawn to an isolated replication competent recombinant virus comprising a paramyxovirus genome or antigenome and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and one or more recombinant genes or genome segments from human metapneumovirus, classified in class 424, subclass 211.1.

XIII. Claim 57, drawn to a method of screening an antiviral compound for inhibition of a biological activity of a human metapneumovirus comprising providing a rHMPV comprising a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P) and a large polymerase protein (L), and a partial or complete rHMPV genome or antigenome modified to incorporate a detectable heterologous sequence encoding a polypeptide correlated with the biological activity, exposing a sample to a test compound or a library of test compounds to determine inhibition of the biological activity of HMPV by said test compound(s), classified in class 435, subclass 5.

Claims 1-8, 25, 26, 55 and 56 link(s) inventions I-VI. Claims 28 and 29 link inventions VII-VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-8, 25, 26, 28, 29, 55 and 56. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn

and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-X and XII are directed to related rHMPV. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to different rHMPVs having different gene sequences or genomic structures that could result in dramatically different phenotype of said rHMPVs. Therefore, those different rHMPVs can be used in different mode of operation and have different functions. They do not overlap in scope. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus, inventions I-X and XII are patentably distinct from each other.

3. Inventions XI and inventions I-X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the rHMPV in inventions I-X and XII can be used to produce a recombinant protein in vitro or to screen an antiviral compound in immunoassay as opposed to induce an immune response in a subject. Thus, groups XI and groups I-X, XII are patentably distinct from each other.

4. Inventions XIII and inventions I-X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the rHMPV in inventions I-X and XII can be used to produce a recombinant protein in vitro or to induce an immune response in a subject as opposed to screen an antiviral compound in immunoassay. Thus, groups XIII and groups I-X, XII are patentably distinct from each other.

5. Inventions XI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method of inducing an immune response in a subject vs. a method of screening an antiviral compound for inhibition of a biological activity of rHMPV. They are drawn to materially different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different

classifications and require separate search. There would be serious burden for examiner to search both groups. Thus, group XI and group XIII are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER